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Director Center for Device and Radiological Health
Performance Management Status Report
October 1, 2001 - September 30, 2002

#	FY 2002 Goal	Comments on Current Status
I.	**LEADERSHIP IN SUPPORT OF AGENCY STRATEGIC INITIATIVES:**	
	Leads in a proactive, customer-responsive manner consistent with Agency vision and values, effectively communicating program issues to external audiences. Demonstrates prudence and the highest ethical standards when executing fiduciary responsibilities. Uses effective business practices including balance measure of results; values and invests in each employee; provides fair and equitable recognition and equal opportunity; emphasizes empowerment, two-way communication and teamwork.	• CDRH responded 100% on time to executive correspondence. • Partnered with various agencies on developing a Diabetic Web Page that is fully functional. • Completed the Gallup Workplace Survey to build a stronger workplace. • Developed and implemented a Master Reviewer Program for CDRH. • Worked with CDC on several Counter Terrorism • Worked with CMS on developing device technology • Continued mentoring students at Alice Deal Junior High School and Wooten High School science internship students. • Collected wireless telephone phones for distribution to domestic violence victims in the area. • Worked with the Office of Women's Health and community church to establish a program that provides transportation for women to mammography facilities. • As of October 2002, CDRH obligated 100% of its total resources. CDRH's operating and payroll resources totaled $124,564,836 and our final obligations totaled $124,564,773 leaving a remaining balance of $63.00 or less than 1/10 of 1 percent. • CDRH's cumulative spending by quarter for operating dollars occurred as follows: 1st quarter 24% 2nd quarter 39% 3rd quarter 79% 4th quarter 100% CDRH hired 8 disable employees.
II.	**ENHANCE INDUSTRY COMPLIANCE WITH REQUIREMENTS:**	
A	Ensure 97% of mammography facilities meet inspection standards, with less than 3% with Level I problems. (Joint Responsibility with ORA)	As of 9/30/02 97.4% of the facilities were inspected at 2.6% Level 1 non-compliances. Despite an initial rise in Level I violations caused by the more stringent and more numerous requirements instituted when the final MQSA regulations became effective April 28, 1999, the program once again achieved its performance goal of less than 3% of mammography facilities receiving Level I (serious) violations. By employing strategies that enabled the program to realize greater efficiencies, the program met the goal without an increase in appropriated funding and without an increase in the inspection fee charged to facilities.

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		Strategies employed to bring the serious violation percent back into the goal range included more focus in the training of inspectors towards educating facilities about the new requirements, while at the same time decreasing inspector training costs through the use of on-line training for a portion of the inspector training course. In addition, facility and inspector education and awareness increased through web-based information-sharing initiatives designed to reach the program's wide audience such as a web-based policy guidance search engine and electronic scorecard-type facility feedback.
	Improve Capacities for Sound Inspection and Examination:	
B	Provide inspection coverage for 20% for Class II and Class III domestic medical device manufacturers. (Joint Responsibility with ORA)	Completed 1,059 of the 1,049 targeted statutory firms have been reported as inspected so far (101% of this goal). 982 of these inspections were GMP and PMA inspections (94% of this goal).
C	Provide inspection coverage for Class II and Class III foreign medical device manufacturers at 9% for FY 2002. (Joint Responsibility with ORA)	Completed 209 of the targeted 225 inspections accomplished (93% of this goal). The international climate post 9/11 during the first quarter of FY 2002 adversely impacted foreign inspection travel including inspections associated with this goal.
	Improve Timeliness of FDA Review and Approvals:	
D	Complete 90% of Premarket Approval Application (PMA) first actions within 180 days.	Completed 94% of the PMA first actions within 180 days, exceeding the goal by 4%.
E	Enhance the MeDSuN System by recruiting a cumulative total of 80 hospitals	Enhanced MeDSuN to include 80 facilities.
F	Recognize 20-25 new standards for the device application review process.	CDRH recognizes 57 new standards for the device application review process.
G	Complete 95% of PMA "Determination" meetings within 30 days.	Held one PMA “determination” meeting within 30 days for a completion rate of 100%.
H.	Conduct a cumulative total 290 BIMO inspections with emphasis on vulnerable populations (Joint Responsibility with ORA)	Completed 346 of the targeted 290 BIMO inspections reported as accomplished so far (119% of this goal). CDRH issued sufficient assignments in time for ORA to meet the inspection target.
	Additional Program Goals identified in the FDA Performance Plan (GPRA)	
	Issue guidance on the use of potassium iodide (KI) as a thyroid blocking agent in radiation emergencies. (Jointly with CDER).)	Guidance issued by CDER
	Review and complete 95 percent of PMA supplement final actions within 180 days	Completed 96% of PMA supplement final actions within 180 days on a regular track and 44% within 180 days on a panel track for a combined completion rate of 94%.

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	Review and complete 95 percent of 510(k) (Premarket Notification) first actions within 90 days.	Completed 100% of 510(k) first actions within 90 days.
	Develop Emergency Counter Terrorism Preparedness and Response Plan for radiation.	Several draft CT plans (OEP, FDA, ORA, CDRH) are in place.
	ONE-HHS MANAGEMENT OBJECTIVE/MANAGEMENT IMPROVEMENT INITITIATIVE	
1	**RESULTS ORIENTED MANAGEMENT:** Create individual employee contracts that will hold my subordinate managers (SES and equivalents due by 2/28/02) and their employees accountable for achieving the goals contained in Dr. Crawford's performance contract.	All contracts in place. CDRH Office Director's plans attached.
2	**PROGRAM SUPPORT AND ADMINISTRATIVE EFFICIENCIES:** • Ensure compliance with all HHS policies on travel and real property.	CDRH is in compliance with all HHS policies. All capitalized property was accounted for during FY 2002 audit.
	• Cooperate as needed with contractor studying consolidation of administrative functions	• CDRH is represented on the steering committee studying administrative consolidation. • CDRH participated in a one-day go-away with Booz-Allen Hamilton as well as individual management with center staff to prepare for administrative consolidation.
3	**STRATEGIC HUMAN CAPITAL MANAGEMENT:**	
	• Conduct hiring in skills areas to support assigned 2002 Hiring Plan target (You must include the specific target for your Center in this section)	The FY 02 Hiring Plan identified 82 hires - CDRH hired 64. CDRH has met or exceeded the hiring plan in the Information Technology Specialists, Medical Officer, Chemist, and Patco 3 & 4 (clerical) categories, as well as the Commissioned Corps categories. In addition, CDRH hired 14 of the 16 positions identified in the Professional/Scientific/Engineer category.
	• Provide specific Center targets for participation in innovative programs developed by OHRMS to recruit and retain staff.	• Completed CDRH targets. • Hired 8 disabled persons.
	• Implement plan to delayer CDRH, in reducing manager-employee ratio in administrative functions.	• CDRH continues to monitor the manager-employee ratio. • Reorganization in OMS resulted in a reduced manager to employee ratio in the administrative area. • Anticipate some reduction with the establishment of the new IVD Office.
	• Recommend and award SES rank and merit awards based on achievement of performance goals in	All direct reports are rewarded based on accomplishments as defined in their performance plans

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	performance contracts.	
	• Participate in labor management discussions at the Agency level on uniformity of labor contracts.	• Center participates in relevant discussions at Agency Level. • Personally chairs FDA Safety Advisory Board and the National Health and Safety Advisory Committee.
	• Provide specific Center goals for increasing the percentage of Center employees receiving training through distance learning vehicles.	• CDRH active users of DL/NET increased by 26%. Since the posting of the CDRH Employee Orientation Webcast Series on the Intranet, 16% of CDRH has accessed 8 sections of Employee Orientation Program. • Provided over 85 training programs for CDRH employees
5	**CONTRACTING AND COMPETITIVE SOURCING:**	
	• Encourage project officers to attend Performance Based Contract (PBC) training classes, to convert applicable contracts to PBC, and to cooperate with any conversions recommended by OFAC	• CDRH has trained over 50% of the centers project officers in performance - based contracts. • CDRH appreciably increased it's percentage of service contract dollars awarded for performance-based contracts from 0% in FY'01 to 20% in FY'02. Three new CDRH performance-based service contracts were negotiated and awarded in FY 2002 totaling over $2.2 Million and this total represents 20% of our eligible service contract dollars.
	• Cooperate in identifying firms in the various Small Business Administration categories and use these firms whenever possible.	CDRH continued to cooperate in identifying firms in the various Small Business Administration categories and used these firms whenever possible as contracting sources. Of particular note, 7 new small business contracts were negotiated and awarded in FY 2002 totaling over $6,450,000.
	• Work with contractor to develop Most Efficient Organization (MEO) in the following commercial areas identified in "Summary of FDA Commercial Activities 2002" for competitive sourcing: Television Studio - Library Services - Web Design and Development – Systems, Design, Development & Programming Services	CDRH has participated with the Agency in identifying commercial activities to be studied in order to meet the 2002 OMB goal of studying 5% of the positions in FDA that perform commercial activities. In addition to the orientation and training provided by Management Analysis, Inc (MAI), the FDA contractor, for those individuals impacted by the A-76 commercial activities studies, CDRH arranged for an additional briefing by MAI to respond to questions and concerns about the process. Some of the issues identified at this meeting were forwarded to FDA, to address. CDRH's Executive Officer also held a meeting with all employees impacted by the A-76 initiative to respond to questions and concerns. Representatives from CDRH have been identified and are currently participating on the study teams for the 3 activities subject to competitive sourcing: CDRH TV Studio; Library Services and Web Publishing. The CDRH Executive Officer serves as a member of the A -76 Steering Committee. CDRH has participated in the certification of the two MEO's that have been presented for approval (library & web publishing).
	• Train Center staff, as rollout progresses to expand	Rollout of PRISM's software has not occurred.

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	online procurement with PRISM (Automated procurement system).	
6	**INFORMATION TECHNOLOGY MANAGEMENT:**	
	• Dedicate Center staff to project teams, as needed, to implement PeopleSoft.	CDRH employee was assigned to the PeopleSoft project working group and the Center's clean up of the data was completed ahead of schedule.
	• Participate, as requested, in Agency review of existing enterprise licenses for potential cost saving and the development of at least 1 additional enterprise licensing opportunity.	• CDRH joined the NIH Software Deployment Project (Microsoft Enterprise Agreement plan) in FY 02 in order to procure enterprise-wide desktop software. FDA/OIRM provided the introduction to this opportunity enterprise-wide, via the IRM Council, but allowed each Center to participate or not, as they chose. CDRH participation resulted in an annual cost savings to the Center of about 30% when compared to procurement costs for GSA pricing for desktop software licensing. • Oracle products licensing were greatly expanded on an enterprise basis this year; CDRH supported the review and bought in.
	• Evaluate and incorporate, as applicable, new technologies for improved efficiencies.	• The implementation of 3-TB Storage Area Network system for the CDRH computer facilities increased the flexibility and efficiency of available network storage. • The implementation of a 100+ GB email system provides optical-disk-based archiving, significantly increasing storage capacity while decreasing maintenance time. • Successful completed conversion of CDRH desktop and laptop systems from Windows NT to Windows 2000/Office XP.
	• Follow guidelines and ensure Center staff receives training in IT security.	CDRH had a 92% completion rate.
	• Close out 50% of OIG findings related to IT security.	No IT Security findings cited.
	• Provide specific targets to meet E-Government Objective in Dr. Crawford's plan, at a minimum addressing enhanced electronic capacities for submission of product applications.	• CDRH has developed and will be piloting electronic submission software for laser products. The software will be made available to laser product manufacturers via either a web download or by requesting a copy on a CD. The software: presents a layout of the reporting guide and leads the user through specific sections and questions; edits responses for completeness and erroneous responses; permits attachments of files such as user guides; will not permit submission of an incomplete report or one containing certain types of errors; saves the complete submission on the manufacturer's hard drive, permitting creation of a complete submission on a CD. Once received in CDRH: The submission is checked for viruses; an acknowledgement letter is automatically generated to the manufacturer; review staff are notified of the new incoming report; The submission is checked for

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		potential non-compliances and assigned a numeric score that is used by the review staff for triaging submissions for review; An Oracle database is populated with technical data extracted from the submission. The pilot with approximately 25 manufacturers is due to begin in July. Future enhancements are in the planning stage and awaiting evaluation of the pilot and approval of funding. The pilot software has undergone enhancements with added features prior to releasing the software to manufacturers. The release date was extended to the week of October 14th. • A CDRH Task Force is also developing a concept paper proposing that e-submission of Special 510(k) be the next e-submission effort. It is expected that a number of 510(k) product submissions will be based on the eLaser architecture and platform. The concept paper has been developed and is currently under review. • The CDRH website was completely redesigned to categorize information in a simpler, more straightforward manner, become more user-friendly, and to assure adherence to usability and Section 508 standards. • CDRH developed a mechanism for searching the CFR several different ways, by Regulation number, Parts, Sections, words or phrases. This is a vast improvement upon the mechanism provided by the Government Printing Officer, and has also been added to FDA's home page. • CDRH continues to pursue new approaches to simplify finding information on the website, such as our prototyping a "super search" that allows industry (and all users) to find all information in our databases about a given device or company with a single search screen.
8	**IMPROVED FACILITY MANAGEMENT AND SECURITY:**	
	• Participate with OFACS in auditing 100% of Center facilities for compliance with DOJ level-special minimum-security requirements.	The Center participated with OFACS in an audit of security requirements for all of our buildings and we are in the process of making modifications to Center facilities to comply with the DOJ requirements.
	• Encourage Center employees to respond to Employee Satisfaction Survey on security services.	The Center continues to promote energy reduction by utilizing technology such as automated listings control.
9	**FAITH/COMMUNITY-BASED PARTNERSHIPS:**	CDRH had several partnerships with organizations in the community. Some

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	• Participate with OFACS on workgroups for data gathering and identification of faith/community-based organizations.	examples include: • Continued mentoring students at Alice Deal Junior High School and Wooten High School science internship students. • Collected wireless telephone phones for distribution to domestic violence victims in the area. • Worked with OWH and community church for scheduling transportation for women screening test.